Message (Digitally Signed)

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Sent: 5/14/2020 2:36:29 PM
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CC: Bernard Gadagbui [gadagbui@tera.org]; Pat McGinnis [mcginnis@tera.org]; Chijioke Onyema [onyema@tera.org]
Subject: Re: Chlorpyrifos & EPA's Science Transparency Rule
Attachments: smime.p7s

Dear Colleagues

Below are comments to EPA on its science transparency rule. Since we used chlorpyrifos as an example, we thought it best to share with you.

Cheers!

Michael…

... L. Dourson, Ph.D., DABT, FATS, FSRA
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Agency: Environmental Protection Agency (EPA)
Document Type: Rulemaking
Title: Strengthening Transparency in Regulatory Science
Document ID: EPA-HQ-OA-2018-0259-9322

Comment:
EPA's science transparency rule is reasonable for risk judgment

Dear Colleagues,

We, fully support, with one enhancement, EPA's science transparency rule announced at https://www.epa.gov/osa/strengthening-transparency-regulatory-science. The principal reason for our support is that any one study, especially one with significant societal impact, should be sufficiently robust so that it can be replicated, if needed, with similar/same results, because positive findings can occur, on average, in one out of every 20 studies due to chance (Randall and Welser, 2018). If a study cannot be replicated, when needed, and many of them cannot for a variety of reasons, then the study results need to be consistent with scientific knowledge of the chemical/agent, and the pattern of available data. In addition, the results need to be shared in an appropriate manner so that scientists within federal agencies charged with the protection of public health can peer review and verify the results, or explain discrepancies with other studies or findings.
A case in point is the publication of human studies on chlorpyrifos that show an unexpected effect (Rauh et al., 2011). The findings have not been replicated nor are they consistent with other studies that point to changes in a blood enzyme (cholinesterase) as the first adverse effect at higher exposures. EPA scientists requested the underlying data from the authors in order to confirm the adverse effect purported to occur at lower doses. The authors demurred citing confidentiality concerns, despite EPA policies and procedures long in place to handle confidential information. Thus, EPA chose not to use the results from this human study in their regulatory decision-making.

A recent publication confirms this EPA decision. Since the underlying data were not made available, Dourson et al. (2020) extracted data from the published figures of Rauh et al. (2011) and found a significant portion of data apparently excluded. Moreover, the reported associations of chlorpyrifos levels with health effects could not be fully replicated. Dourson et al. (2020) also requested access to the data from Raul et al. so that confirmation could be attempted, but received no response. The apparent incomplete data, inconsistency with cholinergic responses as the first adverse effect in other research, and lack of communication, including on-again-off again correspondence between the journal editor and Professor Rauh regarding an invited letter to the editor, raise concerns about data transparency by the authors.

From our perspective, EPA's decision not to use such studies, suitably redacted to protect confidential information, is appropriate. The public's interest is best served when science is replicable and consistent with other information. When studies cannot be replicated or when such studies are not consistent with other information, using such studies then depends on having access to the underlying data for independent analysis. When the underlying data are not provided, it is difficult to use such studies to make a credible risk judgment for human health, much less national rulemaking.

In short, the public is often worried about chemical exposure, as they should be when such exposure exceeds a safety level. However, protection of the public is best served by trusting experts dedicated to public health and sharing of data and findings, not by withholding scientific data or avoiding rigorous discussions or independent analysis.

We encourage EPA to proceed with this rulemaking and to expand its procedures for protecting confidential business information to include suitably redacted, personal medical information.

Sincerely,

Michael L. Dourson, Ph.D., DABT, FATS, FSRA
Bernard K. Gadagbui, MS, PhD, DABT, ERT
Patricia M. McGinnis, PhD, DABT
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References

Dourson, M., B. Gadagbui, C. Onyema, and P. McGinnis. 2020. A Commentary on Some Epidemiology Data for Chlorpyrifos. Regulatory Toxicology and Pharmacology. Volume 113, June 2020, 104616. [For a short version see: [For a short version see: https://www.pubfacts.com/detail/visualize/32119975]

Randall, D. and C. Welser. 2018. The Irreproducibility Crisis of Modern Science: Causes, Consequences, and the Road to Reform. National Association of Scholars. ISBN: 978-0-9986635-5-5, April 17.

Rauh, V., S. Arunajadai, M. Horton, F. Perera, L. Hoepner, D.B. Barr, and R. Whyatt. 2011. Seven-Year Neurodevelopmental Scores and Prenatal Exposure to Chlorpyrifos, a Common Agricultural Pesticide, Environ Health Perspectives. 119(8): 1196-1201. doi:10.1289/ehp.1003160.

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